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Attorney #: 2156

Client.Matter #: 108140.00030

Rochelle Seide
 212.484.3945 (BRI CT)
 212.484.3990 FAX
 seide.rochelle@arentfox.com

PLEASE DELIVER TO:

| | | |
|--|----------------|-----------------------|
| Name: | Fax Number: | U.S. Application Nos: |
| Commissioner for Patents U.S. Patent and Trademark Office | (571) 273-8300 | 10/695194 |

Attorney Docket No.: 108140.00030 Group Art: 1645 Examiner: Rodney P. Swartz

Hard Copy Sent: No

Comments:

We are forwarding herewith a Facsimile Transmittal Cover Sheet submitting:

- 1) Petition to Withdraw The Holding of Abandonment;
- 2) Notice of Abandonment Under 37 CFR 1.53 (f) or (g);
- 3) Copy of Credit Card Statement;
- 7) Amendment dated January 11, 2007;
- 8) Petition for Extension of Time (one month \$60.00);
- 9) Copy of Acknowledgement Receipt dated January 11, 2007; and
- 10) Copy of date stamped PDF upload which comprises of 21 pages.

I hereby certify that this correspondence is being deposited in the U.S. Patent and Trademark Office via facsimile transmittal to (571) 273-8300 on this date.

Rochelle K. Seide
 Rochelle K. Seide
 Reg. No. 32,300

June 8, 2007

Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-----------------|---|--|-------------------|--------------|
| Application No. | : | 10/695,194 | Confirmation No.: | 4418 |
| Applicant. | : | HOCHSTRASSER et al.. | Date: | June 8, 2007 |
| Filed | : | October 28, 2003 | | |
| TC/A.U. | : | 1645 | | |
| Examiner | : | Rodney P. Swartz | | |
| Docket No. | : | 108140.00030 | | |
| Customer No. | : | 38485 | | |
| For | : | DIAGNOSTIC METHOD FOR TRANSMISSIBLE ENCEPHALOPATHIES | | |

ATTN: OIPE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

**PETITION TO WITHDRAW
THE HOLDING OF ABANDONMENT**

Sir:

The present application has been deemed abandoned for failure to timely file a proper reply to the outstanding Office Action dated September 11, 2007. A copy of the Notice of Abandonment is attached indicating that no reply was received.

A response was submitted via EFS to the Patent and Trademark Office on January 11, 2007, with a request for a one month extension of time and the required fee (\$60.00). The extension fee was paid by credit card.

A copy of the EFS receipt is attached. Upon review of the receipt, only 2 pages of the response are indicated as having been received by the PTO. However, applicants had uploaded the full document consisting of more than 2 pages. A copy of the PDF upload which indicates 9 pages is attached. This document comprises the Response, Amendment, Transmittal, and Petition for Extension of Time. Also attached is a copy of the undersigned's credit card statement showing that the extension fees were debited by

NYC 336455.1

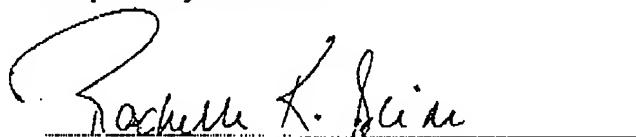
the PTO. All of this indicates that applicants made a good faith effort to timely respond to the Office Action dated September 11, 2006.

A copy of the originally transmitted Response to the Office Action, is enclosed. The papers are dated and certified pursuant to 37 CFR 1.8 as being filed on January 11, 2007.

In view of the above applicants request that the Notice of Abandonment be withdrawn and the application passed onto examination.

Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, referencing Docket Number 108140.00030.

Respectfully submitted,



Rochelle K. Seide, Ph.D.
Registration No. 32,300
ARENT FOX LLP
1675 Broadway
New York, NY 10019
Tel. No. (212) 484-3945
Fax No. (212) 484-3990
Customer No. 38485



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------|-------------|----------------------------|------------------------------|------------------|
| 10/695,194 | 10/28/2003 | Denis Francois Hochbrasser | A36054.PCT-USA-A 072874.0 | 4418 |
| 16485 | 7/29/0 | 06/01/2007 | EXAMINER | |
| AREN'T FOX PLLC | | | SWARTZ, RODNEY P | |
| 1675 BROADWAY | | | | |
| NEW YORK, NY 10019 | | | ARLENE P | PAPER NUMBER |
| | | | 1648 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/01/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| | | |
|------------------------------|--|---|
| Notice of Abandonment | Application No. 10/695,194 Examiner Rodney P. Swartz, Ph.D. | Applicant(s) HOCHSTRASSER ET AL. Art Unit 1645 |
|------------------------------|--|---|

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. Applicant's failure to timely file a proper reply to the Office letter mailed on 11 September 2006.
 - (a) A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection. (A proper reply under 37 CFR 1.113 to a final rejection consists only of; (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(n) and 1.111. (See explanation in box 7 below).
 - (d) No reply has been received.
2. Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) The submitted fee of \$_____ is insufficient. A balance of \$_____ is due. The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) The issue fee and publication fee, if applicable, has not been received.
3. Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) No corrected drawings have been received.
4. The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. The reason(s) below:


RODNEY P. SWARTZ, PH.D
PRIMARY EXAMINER

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

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 Response dated January 11, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Application No. | : | 10/695,194 | Confirmation No.: | 4418 |
| Applicant. | : | HOCHSTRASSER et al. | | |
| Filed | : | October 28, 2003 | | |
| TC/A.U. | : | 1645 | | |
| Examiner | : | Rodney P. Swartz | | |
| Docket No. | : | 108140.00030 | | |
| Customer No. | : | 38485 | | |
| For | : | DIAGNOSTIC METHOD FOR TRANSMISSIBLE ENCEPHALOPATHIES | | |

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

AMENDMENT

Sir:

This paper is submitted in response to the Office action dated September 11, 2006. A one month extension to the time for responding to the Official Action is respectfully requested.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 17 of this paper.

I hereby certify that this correspondence is being deposited in the U.S. Patent and Trademark Office via EFS to the Commissioner for Patents,
 P.O. Box 1450, Alexandria, VA 22313-1450;
 Rochelle K. Seidle, Reg. No. 32390

NYC/298979.1

Appln. No. 10/695,194
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Response dated January 11, 2007

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AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method of diagnosis of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD) or the possibility thereof in a subject suspected of suffering from BSE or CJD the TSE, which comprises subjecting a sample of a body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum taken from the subject to mass spectrometry, thereby to determine a test amount of a polypeptide in the sample, wherein the polypeptide is differentially contained in the body fluid of BSE- or CJD- TSE-infected subjects and non-BSE- or CJD- TSE-infected subjects, and is selected from the group consisting of
 - (a) a polypeptide having a molecular weight of about 1010, 1100, 1125, 1365, 3295, 3645, 3890, 3970, 3990, 4030, 4294, 4315, 4436, 4478, 4780, 5820, 6200, 6700, 7520, 7574, 7630, 7770, 7930, 7975, 7980, 8020, 8600, 8936, 9107, 9145, 9185, 9454, 9950, 10075, 10220, 10250, 11600, 11730, 11800, 13375, 13550, 14043, 15000, 15200, 15400, 15600, 15900, 17839, 30000, 31000 or 31800 Da;
 - (b) cystatin C; and
 - (c) a hemoglobin, a hemoglobin chain, or a truncated chain or fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin; comparing the test amount of the polypeptide in the sample to a reference amount of the polypeptide, wherein the reference amount of the polypeptide represents no BSE or CJD

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TSE infection; and wherein an increase or decrease in the polypeptide in the subject's body fluid compared to the reference indicates BSE or CJD or TSE in the subject.

2. (Currently Amended) The method according to Claim 1, in which the polypeptide is present in the body fluid of BSE- or CJD- TSE-infected subjects and not present in the body fluid of non-TSE BSE- or CJD-infected subjects, whereby the presence of the polypeptide in a body fluid sample is indicative of TSE BSE or CJD.

3. (Currently Amended) The method according to Claim 1, in which the polypeptide is not present in the body fluid of BSE- or CJD- TSE-infected subjects and present in the body fluid of non-TSE BSE- or CJD-infected subjects, whereby the non-presence of the polypeptide in a body fluid sample is indicative of TSE BSE or CJD.

4. (Previously Presented) The method according to Claim 1, in which the mass spectrometry is laser desorption/ionization mass spectrometry.

5. (Previously Amended) The method according to Claim 4, in which the sample is adsorbed on a probe or on a protein chip array having an immobilized metal affinity capture (IMAC), hydrophobic, strong anionic or weak cationic exchange surface capable of binding the polypeptide.

6. (Previously Presented) The method according to Claim 4, in which the

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polypeptide is determined by surface-enhanced laser desorption/ionization (SELDI) and time of flight mass spectrometry (TOF-MS).

Claim 7 (Cancelled)

8. (Previously Presented) The method according to Claim 1, in which a plurality of peptides is determined in the sample.

9. (Previously Presented) The method according to Claim 1, in which the TSE is Creutzfeldt-Jakob disease (CJD).

10. (Previously Presented) The method according to Claim 9, in which the TSE is sporadic Creutzfeldt-Jakob Disease (CJD) or variant Creutzfeldt-Jakob Disease (CJD).

11. (Previously Presented) The method according to Claim 9, in which one or more polypeptides having a respective molecular weight of about 4780, about 6700, about 8600 or about 13375 Da is determined, and the presence of one or more of such polypeptides is indicative of CJD.

12. (Previously Presented) The method according to Claim 9 in which one or more polypeptides having a respective molecular weight of about 3970, about 3990, about 4294, about 4478, about 10075, about 11730, about 14043 or about 17839 Da is

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determined, and the absence of one or more of such polypeptides is indicative of CJD.

13. (Previously Presented) The method according to Claim 9, in which a polypeptide having a molecular weight of about 7770 Da is determined, and the presence of such polypeptide is indicative of CJD.

14. (Previously Presented) The method according to Claim 9, in which a polypeptide having a molecular weight of about 3295, about 4315, about 4436, about 6200, about 8936, about 9107, about 9145, about 9185, about 9454 or about 13550 Da is determined, and the absence or decreased amount of one or more of such polypeptides is indicative of CJD.

15. (Previously Presented) The method according to Claim 9, in which a polypeptide having a molecular weight of about 7574, about 7930, about 7975 or about 8020 Da is determined, and the presence or increased amount of one or more of such polypeptides is indicative of CJD.

16. (Previously Presented) The method according to Claim 1, in which the TSE is Bovine Spongiform Encephalopathy (BSE).

17. (Previously Presented) The method according to Claim 16, in which the polypeptide has a molecular weight of about 10220 Da, and the presence of the

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polypeptide is indicative of BSE.

18. (Previously Presented) The method according to Claim 16, in which one or more polypeptides having a respective molecular weight of about 1010, 1100, 1125, 1365, 3645, 4030, 3890, 5820, 7520, 7630, 7980, 9950, 10250, 11600, 11800, 15000, 15200, 15400, 15600, 15900, 30000, 31000 and 31800 Da is determined, and the differential expression of one or more of such polypeptides is indicative of BSE.

19. (Previously Presented) The method according to Claim 1, in which the TSE is scrapie.

20. (Withdrawn) A method of diagnosis, prognosis or therapy which comprises use of a polypeptide which is differentially contained in a body fluid of TSE-infected subjects and non-infected subjects, the polypeptide having a molecular weight in the range of from 1000 to 100000 and being determinable by mass spectrometry.

21. (Currently Amended) A method of diagnosis, prognosis or therapy of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD) comprising contacting a material which recognizes, binds to or has affinity for a polypeptide which is differentially contained in a body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum of BSE- or CJD- TSE-

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infected subjects and non-infected subjects, the polypeptide being selected from the group consisting of

(a) a polypeptide having a molecular weight of about 1010, 1100, 1125, 1365, 3295, 3645, 3890, 3970, 3990, 4030, 4294, 4315, 4436, 4478, 4780, 5820, 6200, 6700, 7520, 7574, 7630, 7770, 7930, 7975, 7980, 8020, 8600, 8936, 9107, 9145, 9185, 9454, 9950, 10075, 10220, 10250, 11600, 11730, 11800, 13375, 13550, 14043, 15000, 15200, 15400, 15600, 15900, 17839, 30000, 31000 or 31800 Da;

(b) cystatin C; and

(c) a hemoglobin, a hemoglobin chain, or a truncated chain or fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin; and being determinable by mass spectrometry, wherein the amount of polypeptide in a sample is compared to a reference amount of polypeptide wherein the reference amount of polypeptide represents no BSE- or CJD- TSE infection.

22. (Previously Presented) The method according to Claim 21, in which the material is an antibody or antibody chip.

23. (Withdrawn) An assay device for use in the diagnosis of TSE which comprises a plate having a location containing a material which recognizes, binds to or has affinity for a polypeptide which is differentially contained in a body fluid of TSE-infected subjects and non-infected subjects, the polypeptide having a molecular weight in the range of from 1000 to 100000 and being determinable by mass spectrometry.

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24. (Withdrawn) An assay device for use in the diagnosis of TSE, which comprises a plate having a location containing an antibody that is specific for cystatin C.

25. (Withdrawn) An assay device for use in the diagnosis of variant CJD, which comprises a plate having a location containing an antibody that is specific for cystatin C and useful in the diagnosis of variant CJD.

26. (Withdrawn) An assay device for use in the diagnosis of sporadic CJD, which comprises a plate having a location containing an antibody that is specific for cystatin C and useful in the diagnosis of sporadic CJD.

27. (Withdrawn) An assay device for use in the diagnosis of BSE, which comprises a plate having a location containing an antibody that is specific for a hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof having an immunological reaction to antibodies specific for bovine hemoglobin and useful in the diagnosis of BSE.

28. (Withdrawn) An assay device for use in the diagnosis of a TSE comprising a solid substrate having attached thereto an antibody that is specific for any of the following:

- (i) a polypeptide that is differentially contained in the body fluid of TSE-

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infected subjects and non-TSE-infected subjects, and has a molecular weight in the range of from 1000 to 100000;

(ii) a polypeptide that is differentially contained in the body fluid of TSE-infected subjects and non-TSE-infected subjects, and is selected from those having a respective molecular weight of about 1010, 1100, 1125, 1365, 3645, 4030, 3890, 5820, 7520, 7630, 7980, 9950, 10250, 11600, 11800, 15000, 15200, 15400, 15600, 15900, 30000, 31000 and 31800 Da

(iii) cystatin C;

(iv) a hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin and is differentially contained in the body tissue of bovine TSE-infected subjects and non-bovine non-TSE-infected subjects.

29. (Currently Amended) A kit for diagnosis of a TSE selected from the group consisting of BSE and CJD, comprising a probe or protein chip array having an immobilized metal affinity capture (IMAC), hydrophobic, strong anionic, or weak cationic exchange surface capable of binding a polypeptide for receiving a onto which a sample of body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma, and serum is adsorbed, and for placement in a mass spectrometer, thereby to determine a test amount of a polypeptide in the sample, wherein the polypeptide is differentially contained in the body fluid of BSE- or CJD- TSE-infected subjects and non- BSE- or CJD- TSE-infected subjects, and is selected from the group consisting of

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(a) a polypeptide having a molecular weight of about 1010, 1100, 1125, 1365, 3295, 3645, 3890, 3970, 3990, 4030, 4294, 4315, 4436, 4478, 4780, 5820, 6200, 6700, 7520, 7574, 7630, 7770, 7930, 7975, 7980, 8020, 8600, 8936, 9107, 9145, 9185, 9454, 9950,

10075, 10220, 10250, 11600, 11730, 11800, 13375, 13550, 14043, 15000, 15200, 15400, 15600, 15900, 17839, 30000, 31000 or 31800 Da;

(b) cystatin C; and

(c) a hemoglobin, a hemoglobin chain, or a truncated chain or fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin; wherein diagnosis of TSE is determined by comparing the test amount of polypeptide to a reference amount of polypeptide, wherein the reference amount of polypeptide represents no TSE BSE or CJD infection.

30. (Previously Presented) The kit according to Claim 29, in which the probe contains an adsorbent for adsorption of the polypeptide.

31. (Previously Presented) The kit according to Claim 29, further comprising a washing solution for removal of unbound or weakly bound materials from the probe.

32. (Currently Amended) A method of diagnosis of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD) or the possibility thereof in a subject suspected of suffering from the TSE BSE or CJD, which comprises determining

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a test amount of cystatin C in a sample of body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum taken from the subject, wherein the cystatin C is differentially contained in the body fluid of BSE- or CJD- TSE-infected subjects and non-TSE-infected subjects; comparing the test amount of cystatin C in the sample to a reference amount of cystatin C wherein the reference amount of cystatin C represents no TSE BSE or CJD infection; and wherein an increase of cystatin C in the body fluid of the subject indicates TSE BSE or CJD.

33. (Currently Amended) A method of diagnosis of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of BSE Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease (CJD) or the possibility thereof in a subject suspected of suffering from the TSE BSE or CJD, which comprises subjecting a sample of body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum taken from the subject to mass spectrometry, thereby to determine a test amount of cystatin C in the sample, wherein the cystatin C is differentially contained in the body fluid of BSE- or CJD- TSE-infected subjects and non-BSE- or CJD- TSE-infected subjects, comparing the test amount of cystatin C in the sample to a reference amount of cystatin C, wherein the reference amount of polypeptide represents no BSE or CJD TSE infection; and wherein an increase in cystatin C in the body fluid of the subject indicates TSE BSE or CJD.

34. (Previously Presented) The method of claim 33, wherein the body fluid is

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cerebrospinal fluid (CSF).

35. (Currently Amended) A method of diagnosis of Bovine Spongiform Encephalopathy (BSE) or transmissible spongiform encephalopathy (TSE) or the possibility thereof in a bovine subject suspected of suffering from BSE or TSE, which comprises determining a test amount of a polypeptide in a sample of body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum taken from the subject, wherein the polypeptide is differentially contained in the body fluid of BSE TSE-infected bovine subjects and non- BSE TSE-infected subjects, and wherein the polypeptide is selected from the group consisting of a hemoglobin, a hemoglobin chain a truncated chain and a fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin; comparing the test amount of the polypeptide in the sample to a reference amount of the polypeptide, wherein the reference amount of polypeptide represents no BSE TSE infection; and wherein an increase in the polypeptide in the body fluid of the subject indicates BSE TSE.

36. (Currently Amended) A method of diagnosis of a transmissible spongiform encephalopathy (TSE) Bovine Spongiform Encephalopathy (BSE) or the possibility thereof in a bovine subject suspected of suffering from the BSE TSE, which comprises subjecting a sample of body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum taken from the subject to mass spectrometry, thereby to determine a test amount of a polypeptide in the sample, wherein the

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polypeptide is differentially contained in the body fluid of BSE- TSE-infected bovine subjects and non- BSE- TSE-infected subjects, wherein the polypeptide is a hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin; comparing the test amount of the polypeptide in the sample to a reference amount of the polypeptide, wherein the reference amount of polypeptide represents no BSE TSE infection; and wherein an increase in the polypeptide in the body fluid of the subject indicates TSE diagnosis of TSE BSE.

37. (Currently Amended) A method of providing an indication of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD) or the possibility or progress thereof in a subject liable to suffer from BSE or CJD the TSE, which comprises use as a marker of a level of at least one polypeptide that has a molecular weight, of about 1010, 1100, 1125, 1365, 3295, 3645, 3890, 3970, 3990, 4030, 4294, 4315, 4436, 4478, 4780, 5820, 6200, 6700, 7520, 7574, 7630, 7770, 7930, 7975, 7980, 8020, 8600, 8936, 9107, 9145, 9185, 9454, 9950, 10075, 10220, 10250, 11600, 11730, 11800, 13375, 13550, 14043, 15000, 15200, 15400, 15600, 15900, 17839, 30000, 31000 or 31800 Da that is measurable or detectable by mass spectrometry and is differentially contained in a body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum of BSE- or CJD- TSE-infected subjects and non- BSE- or CJD- TSE-infected subjects wherein the amount of

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polypeptide in a sample is compared to a reference amount of polypeptide, wherein the reference amount of polypeptide represents no BSE or CJD TSE infection.

38. (Original) The method of claim 37, wherein said at least one polypeptide is selected from those having a respective molecular weight of about 1010, 1100, 1125, 1365, 3645, 4030, 3890, 5820, 7520, 7630, 7980, 9950, 10250, 11600, 11800, 15000, 15200, 15400, 15600, 15900, 30000, 31000 and 31800 Da.

Claim 39. (Cancelled)

40. (Currently Amended) A method of providing an indication of a transmissible spongiform encephalopathy (TSE) selected from the group consisting of Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease (CJD) or the possibility or progress thereof in a subject liable to suffer from BSE or CJD the TSE, which comprises use as a marker of a level of cystatin C measurable or detectable by mass spectroscopy and is differentially contained in a body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum of BSE- or CJD- TSE-infected subjects and non- BSE- or CJD- TSE-infected subjects wherein the amount of cystatin C in the sample is compared to a reference amount of cystatin C, wherein the reference amount of cystatin C represents no BSE or CJD TSE infection.

41. (Currently Amended) The method of claim 40, wherein the TSE is CJD and

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the body fluid is from a human subject.

42. (Previously Presented) The method of claim 40, wherein the body fluid is cerebrospinal fluid (CSF).

43. (Currently Amended) A method of providing an indication of a-transmissible spongiform encephalopathy (TSE) Bovine Spongiform Encephalopathy (BSE) or the possibility or progress thereof in a bovine subject liable to suffer from the BSE-TSE, which comprises use as a marker of a level of a hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof which exhibits an immunological reaction to an antibody to bovine hemoglobin, said level being measurable or detectable by mass spectroscopy, and said hemoglobin, hemoglobin chain or truncated chain or fragment thereof being differentially contained in a body fluid selected from the group consisting of cerebrospinal fluid (CSF), blood, plasma and serum of bovine BSE-TSE-infected subjects and non-bovine non-BSE-TSE-infected subjects, wherein the amount of hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof in the sample is compared to a reference amount of hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof, wherein the reference amount of hemoglobin, a hemoglobin chain or a truncated chain or a fragment thereof represents no BSE-TSE infection.

44. (Original) The method of claim 43, wherein said hemoglobin, hemoglobin chain or truncated chain or fragment thereof has a molecular weight determinable by

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mass spectroscopy of about 15000 Da, 7500 Da or 3000 Da.

45. (Previously Presented) The method of claim 43, wherein the sample of body fluid is plasma.

46. (Previously Presented) The method of claim 43, wherein the sample of body fluid is from a living animal.

47. (Withdrawn) A bovine animal, or herd of said animals, that has or have been subjected to a test as defined in claim 43 and found to be free of a transmissible spongiform encephalopathy (TSE).

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REMARKS

This is in response to the Office Action mailed September 11, 2006. Thus Applicants request a one-month extension of time for response. The required fee is enclosed.

Claims 1-6, 8-19, 21, 22, 29-38 and 40-46 are being examined on the merits and have been rejected.

Claims 1-6, 8-19, 21, 22, 29-38 and 40-46 have been rejected under 35USC§112 ¶1 as lacking enablement. The Examiner alleges that while the specification is enabling for a specific TSE disease, i.e., BSE and CJD, it is not enabling for any/all TSE diseases as claimed.

In response, applicants have amended the claims to limit them to detection/diagnosis prognosis of BSE or CJD, which are clearly enabled by the specification.

The specification clearly sets out that BSE occurs in cattle while CJD occurs in humans. One of ordinary skill in the art would appreciate that in the case of a human subject, the pattern of differential protein expression from CJD would be used, whereas in cattle one would use the differential protein expression from BSE. Indeed the nature of the examples makes it even more clear as to which pattern one would use based on the species of CSF in the original discovery of the diagnostic differential protein expression patterns.

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Example 1 is entitled "Polypeptides in body fluids (cerebrospinal fluid, plasma and others) of Creutzfeldt-Jakob affected patients", i.e. humans.

Example 2 is entitled "Polypeptides in plasma samples from BSE-infected cattle or non-infected cattle", i.e. cattle.

Each subsequent example clearly shows whether it relates to CJD or BSE and guides one of skill in the art as to which changes in protein expression levels should be used in the methods of the invention, depending on whether the subject being tested is human or is a bovine subject.

Thus, in view of the amendments to the claims and the remarks herein, applicants maintain that the present claims are enabled and request that the rejection for lack of enablement be withdrawn.

Claims 29-31 have been rejected as indefinite pursuant to 35 USC §112 ¶2. The Examiner finds the definition of the "probe" to be unclear.

Applicants have amended the claims to provide more definition to the probe, in that it is a probe or protein chip having certain physiochemical properties such that polypeptides from a subject sample may be adsorbed onto the probe for further characterization, e.g. via mass spectrometry. Support for this amendment may be found in the specification and claims, inter alia, Claims 4-6.

In view of these amendments, applicants maintain that Claims 29-31, as amended, are not indefinite and request that the rejection be withdrawn.

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In view of the amendments to the claims and the remarks herein, Applicants request reconsideration and allowance of the pending claims. A Notice of Allowance is respectfully requested.

Applicants believe that no additional fees (other than the fee for a one-month extension of time for reply) are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, referencing Docket Number 108140.00030.

Respectfully submitted,



Rochelle K. Seide, Ph.D.
Registration No. 32,300
ARENT FOX LLP
1675 Broadway
New York, NY 10019
Tel. No. (212) 484-3945
Fax No. (212) 484-3990
Customer No. 38485

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FEE CALCULATION

Any additional fee required has been calculated as follows:

If checked, "Small Entity" status is claimed.

| | (Column 1) | (Column 2) | (Column 3) | SMALL ENTITY | LARGE ENTITY |
|--|---|---------------------------------------|------------------|--------------|--------------|
| | CLAIMS REMAINING AFTER AMENDMENT | HIGHEST NO. PREVIOUSLY PAID FOR | PRESENT EXTRA | RATE | ADD'L FEE |
| TOTAL CLAIMS | 37 MINUS | 47 | = 0 | x \$25 | \$0.00 |
| INDEP CLAIMS | 12 MINUS | 17 | = 0 | x \$100 | \$0.00 |
| <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM | | | | + \$180 | \$0.00 |
| | | | | | \$0.00 |
| | | | | | |

OR

| | SMALL ENTITY | LARGE ENTITY |
|--|--------------|--------------|
| | RATE | ADD'L FEE |
| | x \$50 | \$ |
| | x \$200 | \$ |
| | + \$360 | \$ |
| | | |

OR

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. 01-2300 referencing docket number 108140,00030.

JUN 8 2007

PTO/SB/22 (06-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

| PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) | | Docket Number (Optional) 108140.00030 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|---------------------------------------|--|-------------------------|-------------------------|---|-------|------|---|-------|-------|---|--------|-------|--|--------|-------|--|--------|--------|---|--|--|--|--|--|--|--|--|--|--|--|---|--|--|
| Application Number | 10/695,194 | Filed October 28, 2003 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| For | DIAGNOSTIC METHOD FOR TRANSMISSIBLE ENCEPHALOPATHIES | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Art Unit | 1645 | Examiner Rodney P. Swartz | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):</p> <table> <thead> <tr> <th></th> <th><u>Large Entity Fee</u></th> <th><u>Small Entity Fee</u></th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1))</td> <td>\$120</td> <td>\$60</td> </tr> <tr> <td><input type="checkbox"/> Two months (37 CFR 1.17(a)(2))</td> <td>\$450</td> <td>\$225</td> </tr> <tr> <td><input type="checkbox"/> Three months (37 CFR 1.17(a)(3))</td> <td>\$1020</td> <td>\$510</td> </tr> <tr> <td><input type="checkbox"/> Four months (37 CFR 1.17(a)(4))</td> <td>\$1590</td> <td>\$795</td> </tr> <tr> <td><input type="checkbox"/> Five months (37 CFR 1.17(a)(5))</td> <td>\$2160</td> <td>\$1080</td> </tr> <tr> <td><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> A check in the amount of the fee is enclosed.</td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.</td> <td></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>01-2300 (Referencing Docket No. 108140.00030)</u>. I have enclosed a duplicate copy of this sheet.</td> <td></td> <td></td> </tr> </tbody> </table> <p>WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>I am the <input type="checkbox"/> applicant/inventor. <input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96). <input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>32,300</u> <input type="checkbox"/> attorney or agent under 37 CFR 1.34 Registration number if acting under 37 CFR 1.27 _____</p> <p> Signature _____</p> <p>Rochelle K. Seide, Ph.D. _____ Typoed or printed name _____</p> <p>(212) 484-3945 _____ Telephone Number _____</p> <p>January 11, 2007 Date</p> | | | | <u>Large Entity Fee</u> | <u>Small Entity Fee</u> | <input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1)) | \$120 | \$60 | <input type="checkbox"/> Two months (37 CFR 1.17(a)(2)) | \$450 | \$225 | <input type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$1020 | \$510 | <input type="checkbox"/> Four months (37 CFR 1.17(a)(4)) | \$1590 | \$795 | <input type="checkbox"/> Five months (37 CFR 1.17(a)(5)) | \$2160 | \$1080 | <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | | | <input type="checkbox"/> A check in the amount of the fee is enclosed. | | | <input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. | | | <input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. | | | <input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>01-2300 (Referencing Docket No. 108140.00030)</u> . I have enclosed a duplicate copy of this sheet. | | |
| | <u>Large Entity Fee</u> | <u>Small Entity Fee</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> One month (37 CFR 1.17(a)(1)) | \$120 | \$60 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Two months (37 CFR 1.17(a)(2)) | \$450 | \$225 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Three months (37 CFR 1.17(a)(3)) | \$1020 | \$510 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Four months (37 CFR 1.17(a)(4)) | \$1590 | \$795 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Five months (37 CFR 1.17(a)(5)) | \$2160 | \$1080 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> A check in the amount of the fee is enclosed. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number <u>01-2300 (Referencing Docket No. 108140.00030)</u> . I have enclosed a duplicate copy of this sheet. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. See below.

Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Acknowledgement ReceiptThe USPTO has received your submission at **12:56:05** Eastern Time on **11-JAN-2007**.\$ **60** fee paid by c-Filer via RAM with Confirmation Number: 1390.**eFiled Application Information**

| | |
|---|---|
| EFS ID | 1431875 |
| Application Number | 10695194 |
| Confirmation Number | 4418 |
| Title | Diagnostic method for transmissible spongiform encephalopathies |
| First Named Inventor | Denis Francois Hochstrasser |
| Customer Number or Correspondence Address | 38485 |
| Filed By | Rochelle K. Seide/Lisa Davis |
| Attorney Docket Number | A36054-PCT-USA-A 072874.0 |
| Filing Date | 28-OCT-2003 |
| Receipt Date | 11-JAN-2007 |
| Application Type | Utility |

Application Details

| Submitted Files | Page Count | Document Description | File Size | Warnings |
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| fee-info.pdf | 2 | Fee Worksheet (PTO-06) | 8182 bytes | ◆ PASS |

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If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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